

1 Cabinet for Health and Family Services

2 Office of Health Policy

3 (Amendment)

4 900 KAR 6:125. Certificate of Need annual surveys, and registration requirements for
5 new Magnetic Resonance Imaging units.

6 RELATES TO: KRS 216B.010, 216B.040

7 STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 216B.040(2)(a)1

8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the
9 Cabinet for Health and Family Services to administer Kentucky's Certificate of Need
10 Program and to promulgate administrative regulations as necessary for the program.

11 This administrative regulation establishes voluntary ~~[the requirements for]~~ registration of
12 Magnetic Resonance Imaging units and the requirements for submission of annual
13 survey data that are used to produce annual reports necessary for the orderly
14 administration of the Certificate of Need Program.

15 Section 1. Definitions. (1) "Cabinet" is defined by KRS 216B.015(5).

16 (2) "Days" means calendar days, unless otherwise specified.

17 (3) "Exempt physicians" means physicians that operate a Magnetic Resonance
18 Imaging unit pursuant to the exemption allowed in KRS 216B.020(2)(a).

19 (4) "Long term care facility" means any entity with licensed long term care beds
20 including nursing facility, nursing home, intermediate care, Alzheimer's, intermediate
21 care facility for the mentally retarded, or personal care.

1 (5) "Office of Inspector General" means the office within the Cabinet for Health and
2 Family Services that is responsible for licensing and regulatory functions of health
3 facilities and services.

4 (6) "Owner" means a person as defined in KRS 216B.015(21) who is applying for
5 the certificate of need and will become the licensee of the proposed health service or
6 facility.

7 (7) "Year" means a calendar year from January 1 through December 31.

8 Section 2. Entities Completing Surveys. The following entities shall submit annual
9 surveys:

10 (1) Licensed Ambulatory Surgery Centers;

11 (2) Licensed Hospitals performing ambulatory surgery services or performing
12 outpatient surgical services;

13 (3) Licensed Home Health Agencies;

14 (4) Licensed Hospice Agencies;

15 (5) Licensed Hospitals;

16 (6) Licensed Private Duty Nursing Agencies;

17 (7) Facilities with licensed long term care beds;

18 (8) Entities that hold a certificate of need for MRI equipment;

19 (9) Facilities with Megavoltage Radiation equipment;

20 (10) Licensed Psychiatric Residential Treatment Facilities; and

21 (11) Facilities with Positron Emission Tomography equipment.

22 Section 3. Entities completing surveys on a voluntary basis. Exempt physicians that
23 have MRI equipment may submit surveys on a voluntary basis.

1 Section 4. Annual Survey Submission. Entities Completing Surveys on a Voluntary
2 Basis. Exempt physicians that have MRI equipment shall submit surveys on a voluntary
3 basis. An annual survey shall be completed for the previous year and transmitted
4 electronically by accessing the Office of Health Policy's Web site at
5 <http://chfs.ky.gov/ohp>.

6 Section 5. Surveys shall be submitted annually as follows:

- 7 (1) Annual Survey of Licensed Ambulatory Surgical Services;
- 8 (2) Annual Survey of Licensed Home Health Services;
- 9 (3) Annual Survey of Hospice Providers;
- 10 (4) Annual Survey of Licensed Hospitals;
- 11 (5) Annual Survey of Licensed Private Duty Nursing Agencies;
- 12 (6) Annual Survey of Long Term Care Facilities;
- 13 (7) Annual Survey of Magnetic Resonance Imaging (MRI) Equipment and Services;
- 14 (8) Annual Survey of Megavoltage Radiation Services;
- 15 (9) Annual Survey of Psychiatric Residential Treatment Facilities; and
- 16 (10) Annual Survey of Positron Emission Tomography (PET) Services.

17 Section 6. Annual surveys shall be completed and submitted no later than March
18 15th of each year. If the 15th falls on a weekend or holiday, the submission due date
19 shall be the next working day.

20 Section 7. Extensions for Survey Submission. (1) A request for an extension for
21 submission of data shall be made in writing or via email to the administrator of the
22 specific survey.

- 23 (2) The request for an extension shall state the facility name, survey log-in

1 identification number, contact person, contact phone number, contact email address,
2 and a detailed reason for the requested extension.

3 (3) One extension per survey of up to 10 (ten) days shall be granted.

4 (4) An additional extension shall only be granted if circumstances beyond the
5 entity's control prevents timely completion of a survey.

6 Section 8. Data Corrections to Draft Annual Reports Utilizing Data Submitted in the
7 Annual Surveys. (1)(a) Prior to the release of draft reports to facilities for their review,
8 the Office of Health Policy shall review data for completeness and accuracy.

9 (b) If an error is identified, the facility shall be contacted by the Office of Health
10 Policy and allowed fourteen (14) days to make corrections.

11 (2)(a) Prior to publication of the reports, the Office of Health Policy shall publish draft
12 reports available only to the entities included in each individual report.

13 (b) The facilities shall be notified of a website and provided with a login identification
14 and password required to access each applicable draft report and shall have fourteen
15 (14) days to review their data for errors.

16 (c) Corrections shall be submitted in writing or via email to the Office of Health
17 Policy before the expiration of the fourteen (14) day review period.

18 (3)(a) After publication of the reports, reports shall not be revised as a result of data
19 reported to the Office of Health Policy incorrectly by the facility.

20 (b) Corrections received after the fourteen (14) day review period shall not be
21 reflected in the published report.

22 (c) Facilities may provide a note in the comments section for the following year's
23 report, referencing the mistake from the previous year.

1 Section 9. Annual Reports. (1) Utilizing data submitted in the annual surveys, the
2 Office of Health Policy shall publish reports annually as follows:

3 (a) Kentucky Annual Ambulatory Surgical Services Report;

4 (b) Kentucky Annual Home Health Services Report;

5 (c) Kentucky Annual Hospice Services Report;

6 (d) Kentucky Annual Hospital Utilization and Services Report;

7 (e) Kentucky Annual Private Duty Nursing Agency Report;

8 (f) Kentucky Annual Long Term Care Services Report;

9 (g) Kentucky Annual Magnetic Resonance Imaging Services Report;

10 (h) Kentucky Annual Megavoltage Radiation Services Report;

11 (i) Kentucky Annual Psychiatric Residential Treatment Facility Report; and

12 (j) Kentucky Annual Positron Emission Tomography Report.

13 (2) Electronic copies of annual reports may be obtained at no cost from the Office of
14 Health Policy's Web site at <http://chfs.ky.gov/ohp>. A paper copy may be obtained for a
15 fee of twenty (20) dollars at the Cabinet for Health and Family Services, Office of Health
16 Policy, 275 East Main Street 4WE, Frankfort, Kentucky 40621.

17 Section 10. Any facility, other than an exempt physician that has MRI equipment,
18 that fails to complete a required annual survey shall be referred to the Office of
19 Inspector General for further action which may impact the facility's license renewal as
20 provided for in 902 KAR 20:008, Section 2(6).

21 Section 11. Magnetic Resonance Imaging Equipment Registration on a voluntary
22 basis by exempt physicians that have MRI equipment.

23 (1) An exempt physician who uses a Magnetic Resonance Imaging unit (MRI) may

1 register the MRI equipment by disclosing the following information by telephone contact
2 and followed up in writing to the Cabinet for Health and Family Services:

3 (a) Name, address, and telephone number of the facility at which each unit is
4 located or to be utilized;

5 (b) Identification of designated contact person or authorized agent of each facility;

6 (c) Make, model, and serial number of each unit;

7 (d) Date the unit became operational at each site; and

8 (e) Whether the unit is free-standing or mobile. If the unit is mobile, the submission
9 shall also identify the number of days the unit is operational.

10 (2) Within thirty (30) days of a change in the facility's address or the addition of
11 another MRI unit as well as the discontinuation of any units, the designated contact
12 person or authorized agent shall notify the Office of Health Policy in writing.

13 Section 12. Incorporation by Reference. (1) The following material is incorporated by
14 reference:

15 (a) "2011 [2040] Annual Survey of Licensed Ambulatory Surgical Services";

16 (b) "2011 [2040] Annual Survey of Licensed Home Health Services";

17 (c) "2011 [2040] Annual Survey of Hospice Providers";

18 (d) "2011 [2040] Annual Survey of Licensed Hospitals";

19 (e) "2011 [2040] Annual Survey of Licensed Private Duty Nursing Agencies";

20 (f) "2011 [2040] Annual Survey of Long Term Care Facilities";

21 (g) "2011 [2040] Annual Survey of Magnetic Resonance Imaging (MRI) Equipment
22 and Services";

23 (h) "2011 [2040] Annual survey of Megavoltage Radiation Services";

1 (i) "2011 [2010] Annual survey of Psychiatric Residential Treatment Facilities"; and

2 (j) "2011 [2010] Annual Survey of Positron Emission Tomography (PET) Services".

3 (2) This material may be inspected, copied, or obtained, subject to applicable
4 copyright law, at the Cabinet for Health and Family Services, 275 East Main Street,
5 Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

900 KAR 6:125

This is to certify that the Executive Director of the Office of Health Policy has reviewed and recommended this administrative regulation prior to its adoption, as required by KRS 156.070(4)

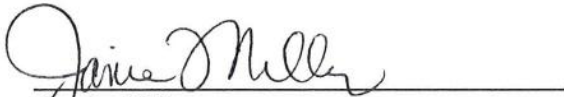
APPROVED:



Carrie Banahan
Executive Director
Office of Health Policy

12/1/11
Date

APPROVED:



Janie Miller
Secretary
Cabinet for Health and Family Services

12/14/11
Date

900 KAR 6:125

A public hearing on this administrative regulation shall, if requested, be held on January 23, 2012, at 9:00 a.m. in the Health Services Building, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by January 16, 2012, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business January 31, 2012. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40621, (502) 564-7905, Fax: (502) 564-7573

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Regulation: 900 KAR 6:125

Contact Person: Carrie Banahan or Chandra Venettozzi, 564-9592

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the requirements for completion of annual surveys and the voluntary registration of new Magnetic Resonance Imaging (MRI) units with the Office of Health Policy.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statute, KRS 216B.010, 216B.062, 216B.990.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 216B.010, 216B.062, 216B.990 by establishing the requirements for completion of annual surveys and the voluntary registration of new Magnetic Resonance Imaging units with the Office of Health Policy for the orderly administration of the certificate of need program.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of KRS 216B.010, 216B.062, 216B.990 by establishing the requirements for completion of annual surveys and the voluntary requirement to register new Magnetic Resonance Imaging units with the Office of Health Policy.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment incorporates by reference the 2011 annual surveys.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary to provide the 2011 version of the annual surveys to entities required to submit annual surveys.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of the authorizing statutes by providing the 2011 version of the annual surveys.

(d) How the amendment will assist in the effective administration of the statutes: This amendment will provide the 2011 version of the annual surveys.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects an entity required to submit annual surveys and an entity wishing to voluntarily register a Magnetic Resonance Imaging unit. Approximately 800 entities complete a survey each year.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the

change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: As the annual survey process and MRI registration process identified in the administrative regulation are already established for all facilities, no action will be required of regulated entities to comply with this regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): As the annual survey process and the registration of MRI units identified in the administrative regulation are already established, no cost will be incurred by regulated entities to comply with this regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This will provide specific instructions for submission of annual surveys and the voluntary registration of new Magnetic Resonance Imaging units with the Office of Health Policy for the administration of the certificate of need program.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No additional costs will be incurred to implement this regulation as we already utilize these surveys and MRI registration process as part of our normal operations.

(b) On a continuing basis: No additional costs will be incurred to implement this regulation on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The source of funding to be used for the implementation and enforcement of this administrative regulation will be from Office of Health Policy's existing budget. As stated above, the annual survey process and voluntary registration of MRI units identified in the administrative regulation are already used as part of our normal operations, so no additional funding will be required.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change if it is an amendment: No increase in fees or funding will be necessary as a result of amendments to this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: No fees are established as a result of amendments to this administrative regulation.

(9) TIERING: Is tiering applied? (explain why or why not) Tiering is not applicable as compliance with this administrative regulation applies equally to all individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 900 KAR 6:125

Contact Person: Carrie Banahan or
Chandra Venettozzi

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

Yes X No

If yes, complete questions 2-4.

2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation affects the Office of Health Policy within the Cabinet for Health and Family Services.

3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.010, 216B.062, 216B.990.

4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative includes a \$20.00 fee for anyone wishing to purchase a paper copy of annual reports. As the reports are available electronically at no cost, the fee is necessary to recoup the agency's printing costs incurred in producing paper reports; therefore, any revenue generated will simply cover the printing costs. There is no net revenue. We anticipate that approximately 40 reports will be purchased.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation includes a \$20.00 fee for anyone wishing to purchase a paper copy of annual reports. As the reports are available electronically at no cost, the fee is necessary to recoup the agency's printing costs incurred in producing paper reports; therefore, any revenue generated will simply cover the printing costs. There is no net revenue. We anticipate that approximately 40 reports will be purchased.

(c) How much will it cost to administer this program for the first year? No additional costs will be incurred to implement this administrative regulation.

(d) How much will it cost to administer this program for subsequent years? No additional costs will be incurred to implement this administrative regulation on a

continuing basis.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

(d) How much will it cost to administer this program for subsequent years? No additional costs will be incurred to implement this amendment on a continuing basis.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES
Office of Health Policy

900 KAR 6:125, Certificate of Need annual surveys, and registration requirements for new Magnetic Resonance Imaging units.

Summary of Changes to Material Incorporated by Reference

1. "2011 Annual Survey of Licensed Ambulatory Surgical Services" is used by licensed Ambulatory Surgery Centers, Licensed hospitals performing ambulatory surgery services or performing outpatient surgical services to submit annual survey information. The following changes were made to the survey:

- Pages 1 through 6 - Revised all 2010 dates to 2011.
- Page 2 - Revised 2011 date to 2012.
- Page 3, Item A, line 3 – Added "Do not include injections."
- Page 5, Item A, line 3 - Added "Do not include injections."
- Page 6, Item B 1. – Added "(exclusive procedure room use)."

The form contains 7 pages.

2. "2011 Annual Survey of Licensed Home Health Services" is used by licensed home health agencies to submit annual survey information. The following changes were made to the survey:

- Pages 1 through 6, 10, 14, 17, and 19 – Revised all 2010 dates to 2011.
- Page 1 – Removed revision date related to administrative regulation.
- Page 2 – Removed revision date related to administrative regulation.
- Page 2 – changed survey due data from March 15, 2011 to March 15, 2012.

The form contains 19 pages.

3. "2011 Annual Survey of Hospice Providers" is used by licensed hospice agencies to submit annual survey information. The following changes were made to the survey:

- Pages 1 through 8 – Revised all 2010 dates to 2011.
- Page 1 – Removed revision date related to administrative regulation.
- Page 2 – Removed revision date related to administrative regulation.
- Page 2 – Changed survey due data from March 15, 2011 to March 15, 2012.
- Page 4, Item 3, - Added a new last sentence to read "Community based hospice facilities are to include all admissions, including those admitted to the residential hospice facilities."
- Page 5 – Revised "Section I-A" to read "Section I".
- Page 6, first paragraph, second sentence - Added "Compassionate Care Center" and "St. Elizabeth Medical Center – Carol Ann & Ralph V. Haile" to list of

separately licensed inpatient facilities. Also, rearranged list so they are in alphabetical order.

- Page 7, first paragraph – Changed “Mountain Community Hospice” to “Mountain Community Hospice Care Center”.

The form contains 8 pages.

4. “2011 Annual Survey of Licensed Hospitals” is used by licensed hospitals to submit annual survey information.

- Pages 1 through 6, 8 through 10, and 12 - Revised all 2010 dates to 2011.
- Pages 2, 4, 6 and 8 - Revised all 2009 dates to 2010.
- Pages 4, 6 and 8 - Revised all 2011 dates to 2012.
- Page 13, last sentence of 3rd paragraph - Revised to read, “Registration of all MRI equipment within the Commonwealth of Kentucky is required for licensed facilities and voluntary for exempt facilities.”

The form contains 14 pages.

5. “2011 Annual Survey of Licensed Private Duty Nursing Agencies” is used by licensed private duty nursing agencies to submit annual survey information.

- Pages 1 through 4 and 7 – Revised all 2010 dates to 2011.
- Page 2 - Removed revision date related to administrative regulation.
- Page 2 – Changed survey due date from March 15, 2011 to March 15, 2012.

This form contains 7 pages.

6. “2011 Annual Survey of Long Term Care Facilities” is used by facilities with licensed long term care beds to submit annual survey information.

- Pages 1 through 8 - Revised all 2010 dates to 2011.
- Page 2 - Revised all 2011 dates to 2012.
- Page 3 - Revised last paragraph to read, “If your facility had a bed change or name change during this 12-month reporting period, please indicate the date and type of change in the comments section. This includes any bed changes for any of the bed types/levels of care (Alzheimers, ICF/MR, Intermediate Care, Nursing Home or Nursing Facility).”
- Page 4 - Revised table to delete SSI as a payor source. SSI was also deleted from Clarification of Primary Payor Source at bottom of page 4.
- Page 5 - Revised all 2009 dates to 2010.

This form contains 8 pages.

7. “2011 Annual Survey of Magnetic Resonance Imaging (MRI) Equipment and Services” is used by entities that hold a certificate of need for MRI equipment and

exempt physicians that have MRI equipment to submit annual survey information.

- Pages 1 through 2, 4, and 6 through 7 - Revised all 2010 dates to 2011.
- Page 2 - Revised to include a new third paragraph that reads as follows, "Submission and completion of the MRI Survey is now voluntary for Exempt MRI facilities. This applies only to those facilities that have ID numbers beginning with EX0."

This form contains 7 pages.

8. "2011 Annual Survey of Megavoltage Radiation Services" is used by facilities with Megavoltage Radiation equipment to submit annual survey information.

- Pages 1 through 5 - Revised all 2010 dates to 2011.
- Page 3 - Revised 2011 dates to 2012.
- Page 4 - Revised definition of simulation to read "**Simulation** – defines location and length/width of field on patient for treatment. Only count those simulations that are performed on the linear accelerator equipment in the gate of the machine."

This form contains 5 pages.

9. "2011 Annual Survey of Psychiatric Residential Treatment Facilities" is used by facilities with licensed Psychiatric Residential Treatment Facility beds to submit annual survey information.

- Pages 1 through 7 – Revised all 2010 dates to 2011.
- Page 3, third bullet – Added "Patients on leave where there is a bed hold should not be counted as a readmission or discharge."
- Page 4, first bullet – Added "Patients on leave where there is a bed hold should not be counted as a readmission or discharge."
- Page 4, fourth bullet – Added "Discharges should match Page 3 discharges line by line."
- Page - Deleted column headings: "Discharged Home, and Discharged Juvenile Treatment Center or Jail" and added column headings: "Discharged Home or Foster Care, Discharged Juvenile Treatment Center, Discharged *SLC Home, and Discharged Residential or Group Home."
- Page 4 – Added footnote "*Discharged SLC – Supports for Community Living Home."
- Page 5, second bullet – Added "Do not include patients coming back from a bed hold."
- Page 6 – Revised 2009 date to 2010 and 2011 dates to 2012.

This form contains 8 pages.

10. "2011 Annual Survey of Positron Emission Tomography (PET) Services" is used by facilities with Positron Emission Tomography equipment to submit annual survey information.

- Pages 1 through 4 - Revised all 2010 dates to 2011.
- Page 2 - Revised 2011 date to 2012.

The form contains 4 pages.

The total number of pages incorporated by reference is 87 pages.